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April 7, 2014

VIA EMAIL AND REGULAR MAIL

Commissioner E. Douglas Varney
Tennessee Department of Mental Health & Substance Abuse Services
Andrew Jackson Building
6th Floor
500 Deaderick Street
Nashville, TN 37243

Re: **Tri-Cities Holdings LLC d/b/a Trex Treatment Center**
CON #1303-005D
Docket No.: T.B.A.

**Tri-Cities Holdings LLC, et al. v. Tennessee Health Services and
Development Agency, et al.
United States District Court (E.D. Tenn.)
Case No. 3:13-cv-305**

Dear Commissioner Varney:

I represent Tri-Cities Holdings LLC d/b/a Trex Treatment Center ("TCH"), the above-captioned applicant. In addition, I also represent eight (8) residents of the Johnson City, Tennessee area who are addicted to opiates and who are recognized as disabled under federal law, including the Americans with Disabilities Act ("ADA") and the Rehabilitation Act of 1973 ("Rehabilitation Act")("Individual Clients").¹

¹ *Mx Group, Inc. v. City of Covington*, 293 F.3d 326, 339 (6th Cir., 2002)(finding opiate-addicted individuals are disabled under the ADA) (citations).

1. The Johnson City area continues to have the highest drug overdose death rate and infant mortality rate in the nation and remains in urgent need of a standard of care, federally-licensed Opiate Treatment Program.

The Johnson City area (northeast Tennessee) continues to be the biggest slaughterhouse of drug overdose death and infant mortality in the United States. In fact, approximately 220 people living in the Eastern District have died of a drug overdose just since the Plaintiffs' Complaint was filed.² Opiate Treatment Programs ("OTPs") can reduce drug overdose deaths in a community by 90%.³ A Wilkes County, North Carolina OTP reduced overdose deaths by 72%.⁴ A Lebanon, Pennsylvania OTP reduced heroin overdose deaths by 100%.⁵ Accordingly, the Johnson City is engaging in what amounts to an illegal, mass ritual *hari kari* (by denying opiate-addicted people access to standard of care medical treatment) that has already killed more than 1,000 of its citizens since 2003 and will surely kill another 1,000 over the next decade. In percentage terms, if the entire United States suffered

² An estimated 10-20 people in the Johnson City area die every month from a drug overdose. Tennessee Department of Mental Health and Substance Abuse Services (Dec. 2012). Northeast Tennessee has at least double the drug addiction treatment rate of the rest of the state. Statewide, three people die a day from overdoses. The Proposed Service Area is 10% of the state, so at least one and, most likely two people die of overdoses every three days in the Proposed Service Area.

³ "Opiate-Dependent Patients On A Waiting List For Methadone Maintenance Treatment Are At High Risk For Mortality Until Treatment Entry." J Addict Med. 2013 May-Jun;7(3):177-82. (The mortality rate (available among 583) during the 2 years on the waiting list was higher (5.0/100 person years) for the 225 non admitted applicants than for the 358 admitted (0.42/100 person years, P < 0.0005) and those who were admitted with no delay before 2002 (2.1/100 person years).)

⁴ "Local Methadone Clinic Helps Reduce Rx Deaths," Wilkes Journal-Patriot, March 12, 2014, http://www.journalpatriot.com/news/article_dbd0f6e8-aa0c-11e3-8435-001a4bcf6878.html. (47 overdose deaths in 2009, the year the clinic was opened, declined to 13 in 2011. Increasing to 24 in 2012 (still a reduction of 48% over 2009). No figures for 2013 available.)

⁵ "Heroin Overdoses Rare in Lebanon County, Thanks To Methadone Clinic," Lebanon Daily News, February 24, 2014, http://www.ldnews.com/local/ci_25058656/heroin-overdoses-rare-lebanon-county-thanks-methadone-clinic?source=email (from 12-15 overdoses deaths each year to zero).

the same death rate of drug overdoses as the Johnson City area, the United States would have suffered more than 500,000 killed by drug overdose in the last decade—a greater loss than in World War II.⁶ Without action, thousands more Tennesseans will surely die unnecessarily.

Over the last decade --and absent fundamental change it will be a never-ending condition -- one to two Johnson City area residents drop dead from a drug overdose every three days.⁷ That's 100-200 dead per year and between 1,000 and 2,000 dead over the next decade. That's on top of the more than 1,000 having died of drug overdoses over the last decade. This is the biggest drug overdose and infant death slaughterhouse in the nation—higher even than the heretofore nation's capital of drug and infant death—West Virginia. HSDA and Johnson City's attorneys want the Court to believe that these horrific drug overdose and infant mortality statistics are just “normal,” “no big deal,” “ho-hum” – simply something “unsolvable” and suffered everywhere. But that is not the case. The drug overdose death and infant mortality in the Johnson City area is much worse than virtually everywhere in of the United States. This at least in some part because there is no standard of care treatment available for opiate addiction, to wit: a federally-licensed Opiate Treatment Program like ones existing in more than 1,300 communities in the United States.

2. The Johnson City area continues to have the highest infant mortality rate in the United States.

Even more depressing than Johnson City area's war-zone-level drug overdose death rate is the area's white, non-Latino infant mortality rate. It's the highest in the nation. Sadly, but almost certainly at least in part because of the denial of access to

⁶ 418,000 U.S. servicemen killed in World War II (http://en.wikipedia.org/wiki/World_War_II_casualties). Proposed Service Area population is 600,000. 1,000 overdose deaths divided by 600,000 equals .16%, then multiplied by U.S. Population of 309,000,000 (U.S. Census Bureau) equals approximately 515,000.

⁷ *Id.* (This estimate is based on the fact that three people die every day in Tennessee from a drug overdose (more than 1,200 annually) and TCH's proposed service area surrounding Johnson City comprises approximately 10% of the state population. So 10% of three deaths a day is approximately one death every three days. This rate is most likely higher than West Virginia, the drug overdose death capital of America. <http://www.ncsl.org/research/health/drug-overdose-death-rate-postcard.aspx>).

standard of care treatment, the Johnson City area suffers the highest non-Latino white infant mortality rate in the United States—higher even than West Virginia-- the heretofore non-Latino white infant death capital of America.⁸ Many third world countries have drastically lower infant mortality rates than the Johnson City area.⁹ A baby in Carter County, Tennessee has essentially the same survival odds as one in Botswana, Africa!¹⁰ The grim figures are below.

<u>Geographic Area</u>	<u>Non-Latino White Infant Mortality per 1,000 Births</u>
Carter County, TN	9.8
Washington County, TN	8.5
Unicoi County, TN	7.7
West Virginia	7.5
Average of TN Counties with MMT	4.4

MMT is unquestionably the standard of care for opiate-addicted pregnant women.¹¹ Despite this obvious fact, a fact that any competent medical provider

⁸ "Chronic Disease Health Profile Regions and Counties" Tennessee Department of Health (2011); Infant Mortality Rates, 2007-2009, The Henry J. Kaiser Family Foundation (kff.org).

⁹ *Id.*

¹⁰ CIA World Factbook (2013), <https://www.cia.gov/library/publications/the-world-factbook/rankorder/2091rank.html> (Botswana suffers an estimated 9.9 deaths per thousand births. Sri Lanka, Saint Kitts and Nevis, Uruguay, Saint Maarten, Costa Rica, Cyprus, Nauru, Ukraine, Macedonia, Latvia, Puerto Rico, Kuwait, Chile, and even Russia, have lower infant mortality rates than the Johnson City area.).

¹¹ In 2012, the American College of Obstetricians and Gynecologists declared in a formal published opinion that MMT is the standard of care for opiate addicted pregnant women: "Opioid use is not uncommon in pregnancy.... The current standard of care for pregnant women with opioid dependence is referral for opioid-

realizes, and in the face of below-third-world infant death rates in the Johnson City area, hundreds of opiate-addicted pregnant women presenting themselves for treatment in the Johnson City area are being illegally denied standard of care MMT treatment for their disability. In fact, in a comically tragic situation, even Johnson City's own large hospital group, Mountain States Health Alliance, declared in a 2012 warning letter to more than 100 doctors in the area not to prescribe sub-standard of care Suboxone and that "Methadone is the recommended medication used for detoxification during pregnancy."¹² Yet, despite this obvious and pathetic lack of standard of care treatment, Johnson City and HSDA plod forward and continue to illegally block access by pregnant women to standard of care treatment.

The Johnson City area's public health statistics related to opiate addiction continue to be horrible—almost uniformly the worst in the nation and way below many third world countries. One would think that common sense would *at least not actively block* standard of care treatment for opiate addiction into the area that is the biggest slaughterhouse of opiate overdose death and infant mortality in the United States. But logic is often scarce in local and state politics. This scenario, sadly, is all too common. In similar fashion, Pakistani villagers recently attacked UN workers bringing standard of care vaccine to areas ravaged by polio.¹³

assisted therapy with methadone.... Abrupt discontinuation of opioids in an opioid-dependent pregnant woman can result in preterm labor, fetal distress, or fetal [death]." "Opioid Abuse, Dependence, And Addiction In Pregnancy," American College of Obstetricians and Gynecologists Committee Opinion No. 524 (2012)(emphasis added). On or about April 30, 2012, the Journal of the American Medical Association declared: "[M]ethadone is the recommended treatment for opioid dependence during pregnancy." On December 9, 2010, New England Journal of Medicine declared: "[T]he standard of care for opiate addiction during pregnancy is methadone maintenance and psychiatric care."¹¹ In 1998, a National Institute of Health (NIH) Consensus Panel declared: "[M]ethadone is the standard of care in pregnant women with opioid addiction." In 2012, the National Institute on Drug Abuse declared: "[M]ethadone has been the standard of care for the past 40 years for opioid dependent pregnant women."

¹² "Women Warned Not to Take Two Drugs Around Pregnancy," *Johnson City Press*, March 22, 2012. (<http://www.johnsoncitypress.com/article/99175>)

¹³Polio Vaccination Teams Attacked by Pakistani Militants, *London Telegraph*, March 1, 2014 (<http://www.telegraph.co.uk/news/worldnews/asia/pakistan/10669840/Polio-vaccination-teams-attacked-by-Pakistani-militants.html>).

3. **Presently, an army of at least 500 disabled persons including pregnant women--and probably more than 1,000—are having to drive 100+ miles roundtrip to North Carolina to receive doctor-prescribed, standard of care, life-saving medication that is not available within 50 miles of Johnson City.**

Presently, an army of at least 500 disabled persons including pregnant women--and probably more than 1,000—are having to get up as early as 1-4AM and drive 100+ miles, as often as daily, to receive doctor-prescribed, standard of care, life-saving medication that is not available within 50 miles of Johnson City.¹⁴ New patients trying to save their lives from opiate addiction must undertake this drive every day for the first 90 days of treatment—requiring them (including pregnant women) to drive over 9,000 miles in the first 90 days of treatment in many cases. Only a sadist could consider this situation acceptable.

Presently, it is undisputed that hundreds of pregnant women are presenting themselves to Johnson City area clinics and emergency rooms each year for treatment of opiate-addiction.¹⁵ Unquestionably, MMT treatment is the standard of care for opiate-addicted pregnant women.¹⁶ But despite the clear and present danger to these women and their babies, standard of care MMT treatment is nowhere to be found for fifty miles in any direction of Johnson City.

¹⁴ These facts were outlined in the CON application, at the June 26, 2013 CON hearing, and letters I sent to HSDA on June 18, 2013 and June 28, 2013 asking for a reasonable modification under the ADA and the Rehabilitation Act.

¹⁵ "Women Warned Not To Use Two Drugs Around Pregnancy," *Johnson City Press*, March 22, 2012 (130 opiate-addicted pregnant women presented themselves for treatment in one recent seven month period).

¹⁶ American College of Obstetricians and Gynecologists (2012) ("The current standard of care for pregnant women with opioid dependence is referral for opioid-assisted therapy with methadone."); Journal of the American Medical Association, April 30, 2012 ("Methadone is the recommended treatment for opioid dependence during pregnancy."); New England Journal of Medicine 363;24 (nejm.org) December 9, 2010 ("The standard of care for opiate addiction during pregnancy is methadone maintenance and psychiatric care."); National Institute of Health (NIH) Consensus Panel (1998) ("Methadone is the standard of care in pregnant women with opioid addiction."); National Institute on Drug Abuse (2012) ("Methadone has been the standard of care for the past 40 years for opioid-dependent pregnant women."))

Instead, the Johnson City and HSDA are forcing opiate-addicted pregnant women to drive long distances to North Carolina OTP clinics for standard of care treatment. This is in spite of the fact that buprenorphine-based treatments carries a significantly higher risk of inducing opiate withdrawal syndrome in some pregnant women. This is a reaction that can kill their baby. Indeed, in 2013, Mountain States Health Alliance warned area doctors of the danger of buprenorphine-based treatments with pregnant women and noted that MMT is the standard of care.¹⁷

TCH's proposed clinic will allow my Individual Clients--along with hundreds of other similarly disabled area residents which include pregnant women – to have access to doctor-prescribed, life-saving, "standard of care"¹⁸ methadone maintenance treatment (MMT) for the first time in the Proposed Service Area.

Presently, this standard of care, life-saving treatment is available only in distant out-of-state clinics (primarily in North Carolina) offering standard of care treatment more than 100 miles roundtrip, over potentially dangerous mountain roads in all weather conditions, from many parts of the proposed service area. At present, MMT standard of care treatment is available at approximately 1,300 clinics across the United States and at least twelve other OTP clinics in other parts of Tennessee. The standard of care for many opiate-addicted persons, and unquestionably for pregnant women, is Methadone Maintenance Treatment ("MMT") that TCH seeks to provide and which is presently unavailable anywhere in the Proposed Service Area.

It's undisputed that there is a "migration" of 400-500 recovering opiate-addicted patients in the Johnson City area who now are being forced to drive more than 100 miles roundtrip, as often as daily, to distant OTP clinics in North Carolina which offer the nearest available of standard of care MMT. These ADA-disabled persons are being exhausted by having to wake up at between 1AM-4AM and embark on these marathon journeys on dangerous mountain roads. Clearly, people are dying

¹⁷ "Women Warned Not To Use Two Drugs Around Pregnancy," *Johnson City Press*, March 22, 2012.

¹⁸ The term "standard of care" treatment is generally recognized as treatment that is accepted by medical experts as a proper treatment for a certain type of disease and that is widely used by healthcare professionals. Standard of care is also called "best practice," "standard medical care," and "standard therapy. National Cancer Institute at the National Institute of Health (<http://www.cancer.gov/dictionary?cdrid=346525>).

because of this exhausted army of disabled people driving on East Tennessee roads as often as daily.¹⁹

4. My clients and others are being illegally forced to drive hundreds of miles over dangerous mountain roads to distant clinics for life saving, doctor-prescribed, standard of care treatment for their disability.

Because between 10 and 20 people living in the Eastern District die from a drug overdose every month, this case directly and daily impacts the lives of real disabled individuals that are being blatantly discriminated against in violation of federal law. This discrimination not only illegally stigmatizes disabled citizens, but risks further death or serious injury to the Individual Plaintiffs, and many others like them by forcing them to drive thousands of unnecessary miles over dangerous mountain roads, in all weather conditions, to the nearest clinics offering standard of care treatment for their disability.

Indeed, this discrimination that denies the disabled local access to treatment has unquestionably resulted in at least one death of even "an innocent bystander" (assuming one considered a disabled addict who just dies of an overdose to be "non-innocent"). A 22-year old married Jonesborough resident, Misty M. Briggs, was killed in a head-on collision with one of the army of approximately 1,000 exhausted opiate-addicted persons having to wake up in the wee hours of the night in the Johnson City area and drive 100+ miles roundtrip, as often as daily, to clinics in North Carolina for life-saving Methadone Maintenance Treatment ("MMT"). "Judge Wants To Look Up Law Before Accepting Plea In Vehicular Homicide Case," *Johnson City Press*, June 29, 2013. The woman who killed Ms. Briggs, Rachel M. Proffitt, 26, a married working mother, has the twin misfortunes of being addicted to opiates and living in an area that denies her reasonable access to MMT. *Id.* This situation forced Ms. Proffitt to wake up at 4AM, drive 60+ miles to Asheville for treatment, then drive 60+ miles back to Johnson City, then drive her husband to work, then drive herself to work, all as often as daily. *Id.* Not surprisingly, one day Ms. Proffitt dozed off at the wheel, veered into oncoming traffic, and killed Ms. Briggs. *Id.* Police blood tests

¹⁹ "Judge Wants to Look Up Law Before Accepting Plea in Vehicular Homicide Case," *Johnson City Press*, June 29, 2013 (Johnson City area woman woke up at 4AM, drove 100 miles roundtrip to North Carolina OTP clinic for standard of care MMT treatment, then drove home, took husband to work, then fell asleep at wheel, crossed center lane, and hit and killed 22-year old Jonesborough woman. Police said blood test results showed exhaustion, not MMT treatment, was to blame).

showed that exhaustion--not methadone--was the cause of the fatal collision. *Id.* Thus, Defendants' policies are unquestionably illegal, but this Court is now presented with substantial and compelling evidence that these policies are killing people. These illegal policies need to be stopped before and further deaths inevitably result. How many more Mistry Briggs are we willing to see killed?

Another "innocent bystander" has been killed by the army of drivers. On March 28, 2014, a Unicoi, Tennessee resident, Tabetha Grindstaff, was killed, and her three passengers, including her two children (age 5 and 9), and an adult male, were severely injured in the crash caused when an area resident receiving methadone treatment fell asleep at the wheel. Based upon available information, area resident Randy Lee Julian was being forced to receive treatment in a distant North Carolina clinic because none is available locally. Mr. Julian, exhausted, fell asleep at the wheel, crossed the center line, and crashed head-on into Ms. Grindstaff's vehicle.²⁰ This daily convoy of a 500-1,000 exhausted disabled drivers causes death with grim regularity.

Many northeast Tennessee communities have enacted blatantly illegal zoning ordinances that discriminate against opiate-addicted, ADA-disabled Americans. These include Church Hill, Morristown, Carter County, Washington County, Johnson City, Unicoi, Kingsport, Bristol, and Rogersville.²¹ These blatant violations are in the midst of area that suffers the highest drug overdose death rate and white, non-Latino infant mortality rate in the nation. An Opiate Treatment Program is also the first-line

²⁰ *Johnson City Press*, March 28, 2014.

²¹ Washington County Zoning Code Section 616.4.3 (no drug treatment clinic within 2,000 of a school, day care facility, park, church, synagogue, mosque, mortuary, amusement facility, or hospital., etc.); Carter County Zoning Code Section 609.1.11 (no drug treatment clinic within 2,000 feet of a school, etc.); Bristol Zoning Ordinance Section 502 (no methadone clinic located within one thousand (1000) feet of a school (public or private) or day care center); Kingsport Zoning Ordinance Section 114-199 (no clinic within 1,000 feet of a school, day care, facility, park, church, synagogue, mosque, mortuary or hospital); Rogersville Zoning Ordinance Section 12-10-13-1 (no drug treatment clinic within 1,000 feet of a school, day care facility, park, church, synagogue, mosque, mortuary or hospital); Town of Unicoi Zoning Ordinances Section 710.4 (no methadone clinic within 1,000 feet of a school, day care facility, park, church, synagogue, mosque, mortuary or hospital); City of Church Hill, Tennessee Zoning Ordinance 09-434 ("[C]linic shall not be located within one thousand (1,000) feet of a school, day care facility, park, church, synagogue, mosque, mortuary or hospital.").

defense in combatting the epidemic of heroin overdose deaths recently declared by Attorney General Eric Holder.²²

Distance is also unquestionably a barrier to treatment so these great distances to treatment lowers treatment rates among recovering addicts. Indeed, Tennessee's own Department of Mental Health and Substance Abuse Services found that retention rates fall in half when patients drive reaches 60 miles one way.²³ So probably another 1,000 to 2,000 disabled people have just given up and gone back to pain pills or heroin to "treat" their addiction.

Opiate addiction--particularly heroin--is growing by the day in the Johnson City area.²⁴ Already, the Johnson City area has the highest drug overdose death rate and the highest infant mortality rate in the nation.²⁵ It's not getting better, it's getting

²² *Attorney General Eric Holder Vows To Fight Rising Heroin Deaths*, CNN, March 10, 2014 (<http://www.cnn.com/2014/03/10/us/holder-heroin-overdose-initiative/>).

²³ Tennessee Department of Health, Methadone Task Force Report (2001).

²⁴ "Heroin Making a Comeback in East Tennessee," Local 8 News, Knoxville, TN, May 17, 2012,

http://www.local8now.com/news/headlines/Heroin_making_a_comeback_across_East_Tennessee_151953835.html; Knoxville Police Indict 19 People In Heroin Drug Ring, WATE Channel 6, Mar 22, 2013, <http://www.wate.com/story/21769200/knoxville-police-indict-19-people-in-heroin-drug-ring>.

²⁵ Johnson City area is the most opiate-plagued in the United States with, most likely, more than 100 oxycodone pills being prescribed per year for every Johnson City area resident over 12 years of age. Two to three Johnson City area residents are dropping dead of a drug overdose every three days. The Johnson City area faces a drug overdose death rate higher than any state in the union. More than 1,000 Johnson City area residents have died of overdoses over just the last decade and another 1,000 will die in the coming decade! There is no place in America when an Opiate Treatment Program is more needed than here.

Crucially, MMT clinics have been shown to reduce drug overdose death rates by ten fold "Opiate-Dependent Patients On A Waiting List For Methadone Maintenance Treatment Are At High Risk For Mortality Until Treatment Entry." J Addict Med. 2013 May-Jun 7(3):177-82. (The mortality rate (available among 583) during the 2 years on the waiting list was higher (5.0/100 person years) for the 225 non admitted applicants than for the 358 admitted (0.42/100 person years, P < 0.0005) and those who were admitted with no delay before 2002 (2.1/100 person years)).

worse.²⁶ And it's about to be hit by a "heroin tsunami" that is already battering communities up and down the East Coast.

On top of an existing opiate-based public health catastrophe, a "heroin tsunami" is now beginning to hit the Johnson City area -- whether we like it or not. First, large numbers opiate addicted persons are being forced out of "pill mills" under a new federal regulatory and prosecutorial crackdown. But shutting down a "pill mill" only compounds the problem. Once an addict is cut off from his supply of opioids—the only alternative is either painful and possibly fatal withdrawal, or, as most do, moving to illegal sources of pain pills or heroin.

Second, heroin is shockingly cheap--only costing about \$10 a dose which are sold in "bags."²⁷ --much cheaper than Suboxone which runs from \$16-22 per day.²⁸

In addition to the highest drug overdose death rate in the nation, the Johnson City area suffers a higher non-Latino white infant mortality rate than any state in the United States—higher even than West Virginia-- the non-Latino white infant mortality capital of America. **A baby in Carter County, Tennessee has essentially the same survival odds as one in Botswana, Africa.** (Botswana suffers an estimated 9.9 deaths per thousand births, CIA World Factbook (2013), <https://www.cia.gov/library/publications/the-world-factbook/rankorder/2091rank.html>). . Many third world countries have drastically lower infant mortality rates. *Id.* The grim figures are below.

<u>Geographic Area</u>	<u>Non-Latino White Infant Mortality per 1,000 Births</u>
Carter County, TN	9.8
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Average TN Cos.with MMT	4.4

²⁶ Tennessee Mental Health and Substance Abuse Services Commissioner E. Douglas Varney Presentation, December 6, 2012 (northeast Tennessee drug addiction rate apparently twice that of rest of state).

²⁷ "A Complicated Actor, Actor Phillip Seymour Hoffman in his Last Days," New York Times, February 6, 2014, <http://www.nytimes.com/2014/02/06/nyregion/a-complicated-actor-philip-seymour-hoffman-in-his-last-days.html>.

Methadone runs about \$12-\$15 per day. Despite this low cost, heroin profits can be enormous²⁹—so the incentive to sell it is enormous and never-ending. Of course, heroin is what killed Academy Award Winner Philip Seymour Hoffman just last month.³⁰ Heroin production has also been mechanized by global drug cartels, making it available almost everywhere.³¹ Most of the heroin sold in the United States is smuggled in through Mexico and then “cut” and distributed in tiny bags in apartments in larger cities than can produce 100,000 bags of heroin a day or more. Heroin is now so ubiquitous in Tennessee, “you can get heroin like ordering a pizza.”³² Recently, one heroin dealer found it convenient to work in McDonalds’ and deliver heroin in Happy Meals to customers using a code phrase “I’d like to order a toy”³³

A heroin epidemic is raging right now. In January, 2014, the Governor of Vermont declared a “full blown heroin epidemic” in his state and devoted essentially his entire State of State Address to the subject of the heroin epidemic in Vermont.³⁴ In February, 2014, the Governor of Maine devoted a large part of his State of the State

²⁸ On Plaintiffs’ information and belief, this is the approximated price a of 16mg dose of Suboxone at CVS Pharmacy (information from Georgia Suboxone seller Reckitt Benckiser sales rep). Methadone runs about \$12 per day at NC clinics.

²⁹ “Heroin costs \$2,600/kilo in Pakistan, but can be sold on the streets of America for \$130,000/kilo (retail).... No agriculture based commodities industry in the world operates on the same price differentials as cocaine and heroin, while requiring relatively little in the way of expertise.” *Frontline* (2014)(pbs.org)(<http://www.pbs.org/wgbh/pages/frontline/shows/drugs/special/math.html>).

³⁰ *Id.*

³¹ “U.S. Efforts Fail to Curtail Trade in Afghan Opium,” *New York Times*, May 26, 2012, <http://www.nytimes.com/2012/05/27/world/asia/drug-traffic-remains-as-us-nears-afghanistan-exit.html?pagewanted=all>.

³² “Heroin Use On Rise In Rural Areas,” *The Tennessean*, February 3, 2014 (“The way that it seems in Nashville, it's like ordering a pizza,' says chief medical officer of Cumberland Heights treatment center.”)

³³ “Pa. Happy Meal Heroin Suspect 'Crushed' by Charges,” *New York Times*, February 11, 2014.

³⁴ Governor Shumin Annual State of the State Address, January 8, 2014 (<http://governor.vermont.gov/newsroom-state-of-state-speech-2013>). Notably, Opiate Treatment Programs are a key part of Vermont’s response to the heroin epidemic.

address to the “troubling [heroin] epidemic... tearing at the social fabric of our communities.”³⁵ On March 10, 2014 U.S. Attorney General Eric Holder declared a nationwide “heroin epidemic.”³⁶ Unless Tennesseans are somehow genetically different than residents of Vermont and Maine—and people living in every other place in America--the heroin epidemic is in the process of exploding here as well. In that case, shouldn’t standard of care methods for treating heroin addiction be available? Johnson City’s and HSDA’s confidence that the heroin epidemic now upon us can be handled in the Norman Rockwell-like settings of small doctors’ offices is sadly misplaced. It’s failed everywhere else--certainly in the face of this area’s catastrophic drug overdose and infant mortality figures—so why is it going to suddenly start working now? As Albert Einstein once famously remarked, “The definition of insanity is doing the same thing, over and over, but expecting a different result.”

It is undisputed that an Opiate Treatment Program offers the strongest, most comprehensive response to wide-spread addiction to opioids as it provides standard of care methadone, testing services, and counseling services to deal with hard-core addiction—heroin addicts and multiple relapse patients.³⁷ In contrast, office-based doctors writing Suboxone prescriptions are not equipped to deal with hardcore heroin users—with risks of relapse on Suboxone almost twice the rate of methadone.³⁸ An office-based doctor usually has no facilities to combat diversion to illegal uses, and no

³⁵ Governor Paul LePage Annual State of the State Address, February 4, 2014 (<https://www.mpbn.net/News/StateoftheStateAddress.aspx>).

³⁶ *Attorney General Eric Holder Vows To Fight Rising Heroin Deaths*, CNN, March 10, 2014 (<http://www.cnn.com/2014/03/10/us/holder-heroin-overdose-initiative/>).

³⁷ National Institute of Drug Addiction International Program, Questions and Answers About Methadone, Part B-1, p. 1,

(2014)(<http://www.drugabuse.gov/sites/default/files/pdf/partb.pdf>) (citations).

³⁸ “Neonatal Abstinence Syndrome after Methadone or Buprenorphine Exposure,” N Engl J Med 363, December 9, 2010 (Treatment was discontinued by 16 of the 89 pregnant women in the methadone group (18%) and 28 of the 86 pregnant women in the buprenorphine group (33%)). Plaintiffs suggest “discontinued” is a euphemism for relapse and return to illegal opiates. Unquestionably, relapse exposes the fetus to much greater risk of death. So Suboxone exposes fetuses to almost double the rate of relapse and death.

institutionalized testing and professional counseling resources that are required by law at an Opiate Treatment Program.

In a situation of particular urgency, right now hundreds of opiate-addicted pregnant women present themselves for treatment every year in the Johnson City area.³⁹ Isn't it reasonable to provide them with standard of care MMT instead of sub-standard Suboxone (a medication with a risk of causing withdrawal and spontaneous abortion of the fetus⁴⁰)

Therefore, TCH, and my individual clients again request that your office provide TCH a reasonable modification or accommodation under the Americans with Disabilities Act ("ADA") and the Rehabilitation Act of 1973 ("RA") to allow TCH to obtain a Certificate of Need and allow it to establish an Opiate Treatment Program (OTP) in Johnson City, Tennessee as requested in its CON application which will allow persons recognized as disabled under the ADA and the RA to have reasonable access to standard of care treatment for their disability. Specifically, I ask that your office amend its earlier report to HSDA which contended there was no need for an Opiate Treatment Program in the proposed service area, that there was no showing that it furthered orderly development of the medical services in the area, and that it was not economically feasible, and/or any other findings or conclusions which serve to block the establishment of this facility in Johnson City.

I understand that your office is in receipt of federal funds which impose similar obligations on your agency under the Rehabilitation Act of 1973 and other federal regulations prohibiting discrimination against disabled persons.

Therefore, on behalf of my clients, I would ask you to provide my clients with a reasonable modification of any and all applicable state and local rules and regulations as required under the ADA and the Rehabilitation Act from your office, and any other applicable agency of the State of Tennessee, to allow TCH to locate its Opiate Treatment Program at 4 Wesley Court, or elsewhere, in Johnson City, Tennessee.

³⁹"Women Warned Not To Use Two Drugs Around Pregnancy," Johnson City Press, March 22, 2012 (Mountain States Health Alliance continues to warn area doctors not to prescribe Suboxone to pregnant women.)

⁴⁰ *Id.*

The Attorney General of the United States, at the instruction of Congress,⁴¹ has issued an implementing regulation that outlines the duty of a public entity to accommodate reasonably the needs of the disabled. The Title II regulation reads:

A public entity shall make reasonable modifications in policies, practices, or procedures when the modifications are necessary to avoid discrimination on the basis of disability, unless the public entity can demonstrate that making the modifications would fundamentally alter the nature of the service, program, or activity.⁴²

This duty to reasonably accommodate is an *affirmative* duty and federal law is *supreme* to any and all Tennessee laws and rules.⁴³ Accordingly, the Supreme Court declared that Title II imposes an “obligation to accommodate,” or a “reasonable modification requirement.”⁴⁴

As directed by Congress, the Attorney General issued regulations implementing title II, which are based on regulations issued under section 504 of the Rehabilitation Act.⁴⁵ The title II regulations require public entities to “administer services, programs, and activities in the most integrated setting appropriate to the needs of qualified individuals with disabilities.”⁴⁶ The preamble discussion of the “integration regulation” explains that “the most integrated setting” is one that “enables individuals with disabilities to interact with nondisabled persons to the fullest extent possible”⁴⁷

⁴¹ See 42 U.S.C. § 12134(a) (“[T]he Attorney General shall promulgate regulations in an accessible format that implement this part.”). The Attorney General’s regulations, Congress further directed, “shall be consistent with this chapter and with the coordination regulations … applicable to recipients of Federal financial assistance under [§ 504 of the Rehabilitation Act].” *Id.* § 12134(b).

⁴² 28 C.F.R. § 35.130(b)(7).

⁴³ *Tennessee v. Lane*, 541 U.S. 509 (2004).

⁴⁴ *Id.* at 532–33; *see also Alexander v. Choate*, 469 U.S. 287, 301 (1995) (suggesting Rehabilitation Act requires “meaningful access” and “reasonable accommodations”); *accord, Ability Center, Toledo v. City of Sandusky*, 385 F.3d 901, 908 (6th Cir., 2004) (“Title II targets more than intentional discrimination....”)

⁴⁵ See 42 U.S.C. § 12134(a); 28 C.F.R. § 35.190(a); Executive Order 12250, 45 Fed. Reg. 72995 (1980), reprinted in 42 U.S.C. § 2000d-1.

⁴⁶ 28 C.F.R. § 35.130(d) (the “integration mandate”).

⁴⁷ 28 C.F.R. Pt. 35, App. A (2010) (addressing § 35.130).

In *Olmstead v. L.C.*, 527 U.S. 581 (1999), the Supreme Court held that title II prohibits the unjustified segregation of individuals with disabilities. The Supreme Court held that public entities are required to provide community-based services to persons with disabilities when (a) such services are appropriate; (b) the affected persons do not oppose community-based treatment; and (c) community-based services can be reasonably accommodated, taking into account the resources available to the entity and the needs of others who are receiving disability services from the entity.⁴⁸

Failure to make a reasonable modification is separate theory of liability under Title II and its implementing regulations. See 28 C.F.R. § 35.130(b) (7). Pursuant to this regulation, federal courts hold that a “failure to accommodate is an independent basis for liability under the ADA.”⁴⁹ To comply with the ADA’s integration mandate, public entities must reasonably modify their policies, procedures or practices when necessary to avoid discrimination.⁵⁰ The obligation to make reasonable modifications may be excused only where the public entity demonstrates that the requested modifications would “fundamentally alter” its service system.⁵¹

In this case, not only did HSDA and Johnson City fail to provide a reasonable accommodation, they failed to even *attempt* one. This is clearly a violation of the ADA and the Rehabilitation Act. By consciously denying disabled persons access to doctor-prescribed, standard of care treatment for their disability, HSDA and Johnson City is attempting to eliminate “undesirable” disabled persons from the community.

⁴⁸ *Olmstead v. L.C.*, 527 U.S. at 607.

⁴⁹ *Sak v. City of Aurelia*, 832 F.Supp.2d 1026 (N.D. Iowa 2011), *citing Wisconsin Community Servs., Inc. v. City of Milwaukee*, 465 F.3d 737, 751 (7th Cir. 2006), *Frame v. City of Arlington*, 657 F.3d 215, 231 (5th Cir. 2011) (noting that Title II does more than prohibit disability discrimination by a public entity, because it “imposes an ‘obligation to accommodate,’ or a ‘reasonable modification requirement,’ ” but expressing no opinion “as to whether (or when) a failure to make reasonable accommodations should be considered a form of intentional discrimination, a form of disparate impact discrimination, or something else entirely”); *Pena v. Bexar County, Texas*, 726 F.Supp.2d 675, 683 (W. D. Tex. 2010) (Title II of the ADA “imposes upon public entities an affirmative obligation to make reasonable accommodations for disabled individuals”) (citing *Bennett-Nelson v. La. Bd. of Regents*, 431 F.3d 448, 454 (5th Cir. 2005)).

⁵⁰ 28 C.F.R. § 35.130(b)(7).

⁵¹ *Id.*; *see also Olmstead*, 527 U.S. at 604-07.

In this case, evidence shows that HSDA and Johnson City intentionally disregarded the plaintiffs' rights. In the alternative, at a bare minimum, HSDA and Johnson City were consciously indifferent to the plaintiffs' claims amounting to intentional discrimination in violation of the ADA and the Rehabilitation Act.⁵²

Under the ADA, a state or local law is "facially discriminatory"⁵³ if it subjects drug treatment programs to more restrictive standards than other comparable facilities.⁵⁴ Such a law violates the ADA unless the treatment program can be shown to pose a direct threat or significant risk to the health or safety of others.⁵⁵ Johnson

⁵²*Duvall v. Cnty. of Kitsap*, 260 F.3d 1124, 1138 (9th Cir.2001) ("To recover monetary damages under Title II of the ADA or the Rehabilitation Act, a plaintiff must prove intentional discrimination on the part of the defendant.... We now determine that the deliberate indifference standard applies." (citations and footnote omitted)). In *Duvall*, the Ninth Circuit held that intentional discrimination can be shown by establishing "deliberate indifference" by the defendant. *Id.* The Duvall court further explained that "[d]eliberate indifference requires both knowledge that a harm to a federally protected right is substantially likely, and a failure to act upon the likelihood." *Id.* at 1139.

⁵³ "[F]acial' challenges to regulation[s] are generally ripe the moment the challenged regulation or ordinance is passed." *Suitum v. Tahoe Reg'l Planning Agency*, 520 U.S. 725, 736 n.10 (1997); see also *Cnty. Concrete Corp. v. Township of Roxbury*, 442 F.3d 159, 164 (3d Cir. 2006)(citations).

⁵⁴ *New Directions Treatment Servs. v. City of Reading*, 490 F.3d 293, 304-05 (3d Cir. 2007); *MX Group*, 293 F.3d at 344-45; *Bay Area*, 179 F.3d at 733-34; see also *First Step, Inc. v. City of New London*, 247 F. Supp. 2d 135 (D. Conn. 2003)*Habit Mgmt. v. City of Lynn*, 235 F. Supp. 2d 28, 29 (D. Mass. 2002). It should be noted that facial discrimination is a type of intentional discrimination claim and can serve as proof of discriminatory intent. *Larkin v. Mich. Dep't of Social Servs.*, 89 F.3d 285, 289 (6th Cir. 1996); *Bangerter v. Orem City Corp.*, 46 F.3d 1491, 1500-01 (10th Cir. 1995); *First Step, Inc.*, 247 F. Supp. 2d at 150-51; *Hispanic Counseling Ctr.*, 237 F. Supp. 2d at 292-93; *Sunrise Dev., Inc. v. Town of Huntington*, 62 F. Supp. 2d 762, 774 (E.D.N.Y. 1999).

⁵⁵ *New Directions*, 490 F.3d at 306-07; *Bay Area*, 179 F.3d at 737; *Habit Management v. City of Lynn*, 235 F. Supp. 2d 28, 29 (D. Mass. 2002). In determining whether a program poses a direct threat to the health or safety of others, a public entity must make an individualized assessment, based on reasonable judgment that relies on current medical knowledge or on the best available objective evidence, to ascertain: the nature, duration, and severity of the risk; the probability that the potential injury will

City's Zoning Ordinance restricting methadone clinics is facially discriminatory because: (1) methadone clinics are subjected to more restrictive zoning standards than comparable medical facilities; and (2) individuals seeking treatment at methadone clinics do not pose a direct threat to the health or safety of others that would justify more burdensome treatment.

Three different circuits – including the Sixth Circuit--have held that restrictions on addiction treatment programs were facially discriminatory because they did not apply equally to comparable programs for people without disabilities. In *MX Group, Inc. v. City of Covington*, the city would not permit the plaintiff to locate a methadone clinic in response to community opposition.⁵⁶

The present situation in Johnson City constitutes a public health catastrophe (with approximately one death from drug overdose occurring in the area every three days) and I would ask you and your office to take immediate action to rectify this dire situation and allow TCH's OTP standard of care program to locate in Johnson City and exist such clinics do in other parts of Tennessee.

5. TDMHSAS is in violation of the ADA and the Rehabilitation Act.

After obtaining the CON from HSDA, TCH is required to obtain a permit from TDMHSAS before opening the OTP in Johnson City. As a part of the CON process, TCMHSAS is supposed to issue a "review and analysis" of an applicant's application supposedly for the benefit of HSDA in assisting in its review process.

On or about March 1, 2013, TCH Manager Steve Kester met with E. Douglas Varney and TDMHSAS staff and specifically requested an opportunity to work with TDMHSAS on TCH's CON application and TDMHSAS permit to allow TCH to locate its OTP in Johnson City. TCH specifically requested that TDMHSAS provide TCH with a reasonable modification, if necessary, to allow the OTP to be opened in Johnson City. TDMHSAS has violated the ADA and the Rehabilitation Act by refusing to provide a reasonable modification to TCH and has actively sought to block TCH from locating an OTP in Johnson City.

actually occur; and whether reasonable modifications of policies, practices, or procedures or the provision of auxiliary aids or services will mitigate the risk.

28 C.F.R. pt. 35 app. A, Section 35.104 (2009); 28 C.F.R. § 35.139 (eff. Mar. 15, 2011).

⁵⁶ 293 F.3d at 329-330.

On about June 11, 2013, TDMHSAS issued a "Review and Analysis of Certificate of Need Application Tri-Cities Holdings LLC d/b/a Trex Treatment Center - CN1303-005" on TCH's CON application ("TDMHSAS Report").

TDMHSAS failed and refused to offer TCH a reasonable modification to allow TCH to locate an OTP in Johnson City. First, the TDMHSAS Report alleged that there was no showing of "need" in TCH's application, even though TCH had shown ample need in the Proposed Service Area for an Opiate Treatment Program. Second, the TDMHSAS Report alleged that there was no showing of "orderly development" in TCH's application, even though TCH had shown clearly that its Opiate Treatment Program would advance the orderly development of medical care in the Proposed Service Area. Third, TDMHSAS refused to find evidence no showing of "orderly development" in TCH's application, even though TCH had shown clearly that its Opiate Treatment Program would advance the orderly development of medical care in the Proposed Service Area. Furthermore, TDMHSAS took an adversarial position against TCH and its application and erected needless barriers to TCH obtaining approval from HSDA. This conduct constitutes a violation of the ADA and the Rehabilitation Act.

In preparing the TDMHSAS Report, TDMHSAS failed and refused at all times to work with and provide TCH a reasonable modification, or even provide TCH with a single opportunity to modify its application to comply with any alleged deficiency in TCH's application, to allow TCH to obtain its CON and locate an OTP in Johnson City.

The administrative hearing officer has scheduled a final hearing on TCH's appeal of HSDA's denial of the Certificate of Need for July 29, 2014. We contend this hearing is illegal on several grounds, including the fact that it is in clear violation of the statutory time limit within which a hearing must be conducted under Tenn. Code. Ann. 68-11-1610(d) and that Judge Summers and the Tennessee Department of Administrative Services failed and refused to comply with the ADA and the Rehabilitation Act of 1973 to offer TCH a reasonable modification to allow it to obtain its Certificate of Need.

TDMHSAS bears an affirmative duty to comply with federal law in this case. TCH will need evidence of your office's reasonable modifications to allow your agency to issue a positive report and to present this positive report at the July 29

hearing. Your agency bears this *affirmative duty* in this case and, respectfully, I submit your agency is already in violation of federal law in the case, and subject to losing federal funds, for failing to comply with this affirmative duty in its findings on TCH's application presented to HSDA. I respectfully ask that you present a modified report within a reasonable time period sufficiently in advance of this hearing date to comply with your agency's obligations under federal law.

If necessary and appropriate, your office can indicate such approval was made to comply with federal law. I would ask that your office contact me to confirm it intends to comply with federal law and its preparations in this regard at your earliest convenience.

Sincerely,
James A. Dunlap Jr. & Associates LLC



James A. Dunlap Jr.

JAD/jd

Cc: Sue Sheldon, Esq., Tennessee Attorney General's Office